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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,573	04/19/2000	Gary K. Michelson M.D.	101.0077-00000	3776

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,573

Applicant(s)

MICHELSON M.D., GARY K.

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34, 36-42 and 101-140 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34, 36-42 and 101-140 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11. 6) ☐ Other:

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DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The following are examples only, it is applicant's duty to assure all claimed element are shown:

Claim 7, leading end is tapered.

Claim 10, curve extends from said exterior sidewall beyond the mid-longitudinal axis.

Claims 11-12, protrusion.

Claim 13, roughenings.

Claim 14, porous surface.

Claim 16, surface protrusions.

Claim 17, porous.

Claim 36, opposed portions are in a diverging relationship.

Claim 37, converging.

Include new claims 102-140 which correspond to the above claims.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Specification

The amendment filed 9/11/02 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The new limitation added to page 17, line 6, describing the opposed portions of the implant can be in a moveable relationship is considered new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, "first distance is greater than the third" is never true.

Claim 4, "approximately equal" is ambiguous and directly conflicts with other claims.

Claims 8 and 9 are not understood. Same for claims 105-106. Please explain.

Claim 35, "hollow interior" is ambiguous as to the indented element. Please direct to the figures and specification for support.

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Claim 39, moveable relationship.

Include claims 102-140 corresponding with the above claims in the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6, 8-13, 15-17, 23-24, 33, 38, 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Albert (FR 2724312).

Referring to figure 1, Albert teaches a spinal implant having a width approximately $\frac{1}{2}$ of the maximum width of the vertebral into which it is intended to be implanted. The implant has a first distance that is greater than a second distance and a third distance greater than said second distance. See attachment of Figure 2 with the Examiner's interpretation.

The implant inherently has opposed portions which maintain a desired height of two adjacent vertebrae. The implant is interpreted as having one large opening in each opposed portion fulfilling the claim language "*said opposed portions having at least one opening therein.*"

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Regarding claim 38, see elements including 24, 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 14, 18-22, 25-32, 34, 36-37, 39, 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert (FR 2703580) in view of Michelson (5,609,635).

Albert discloses the spinal implant as described in the rejections above. However, Albert is unclear the fusion promoting materials used therewith. Michelson teaches different materials, configurations, etc. used with a spinal implant. It would have been obvious to one having ordinary skill in the art to have utilized the roughened surfaces, fillings, or coatings, etc. as taught by Michelson, or known in the spinal art, to enhance fusion between the implant and vertebrae.

Note Michelson, teaches angular relationship of the upper and lower surfaces.

Regarding claim 34, note that Michelson teaches a more extensive opposing surfaces with more than two openings. It would have been obvious to one having

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ordinary skill in the art to have used the more extensive openings of Michelson with the implant of Albert to distribute more weight.

Claims 1-34, 36-42, 101-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson (5,609,635) in view of Kuntz (4,349,921).

Referring to figures 1-17, Michelson teaches a spinal implant having an anterior aspect, a posterior aspect, and sidewalls. Michelson further teaches opposed surfaces having at least one opening and said opposed surfaces can be relatively angled. Michelson further teaches all claimed surfaces, elements, and material. However, Michelson does not teach the implant being less than approximately one-half the maximum width of the adjacent vertebrae.

Kuntz teaches a spinal implant can be formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6. It would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Michelson because "*when a prosthesis for the lumbar area is required, it has been found advantages to make the prosthesis in two halves.*" see column 9, lines 41 **et seq.** In dividing the implant in two halves, it would have been obvious to one having ordinary skill in the art that in some embodiments, interior walls would be formed for structural integrity.

Note figures 12-14 of Kuntz teaching moveable opposing surfaces.

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Response to Arguments

Applicant's arguments filed 9/11/02 and 11/25/02 have been fully considered.

Regarding applicant's argument pertaining to the restriction/species requirement, applicant states that claim 102 is a "linking claim" which is not understood and might be confused with "generic claim".

Applicant's arguments regarding the double patenting rejections were persuasive and have been withdrawn.

Applicant's argument regarding the implant of Gilles (FR 2703580) not comprising two separate halves was persuasive.

Regarding the rejections in view of Albert (FR 2724312), the applicant's arguments are addressed in the grounds of rejection above.

Conclusion

Applicant's amendment, including the amendment to claim 34 claiming at least two openings and the addition of new claims 102-140, necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
January 28, 2003

A handwritten signature in black ink, appearing to be 'Bruce Snow', with a long horizontal line extending to the right.

BRUCE SNOW
PRIMARY EXAMINER

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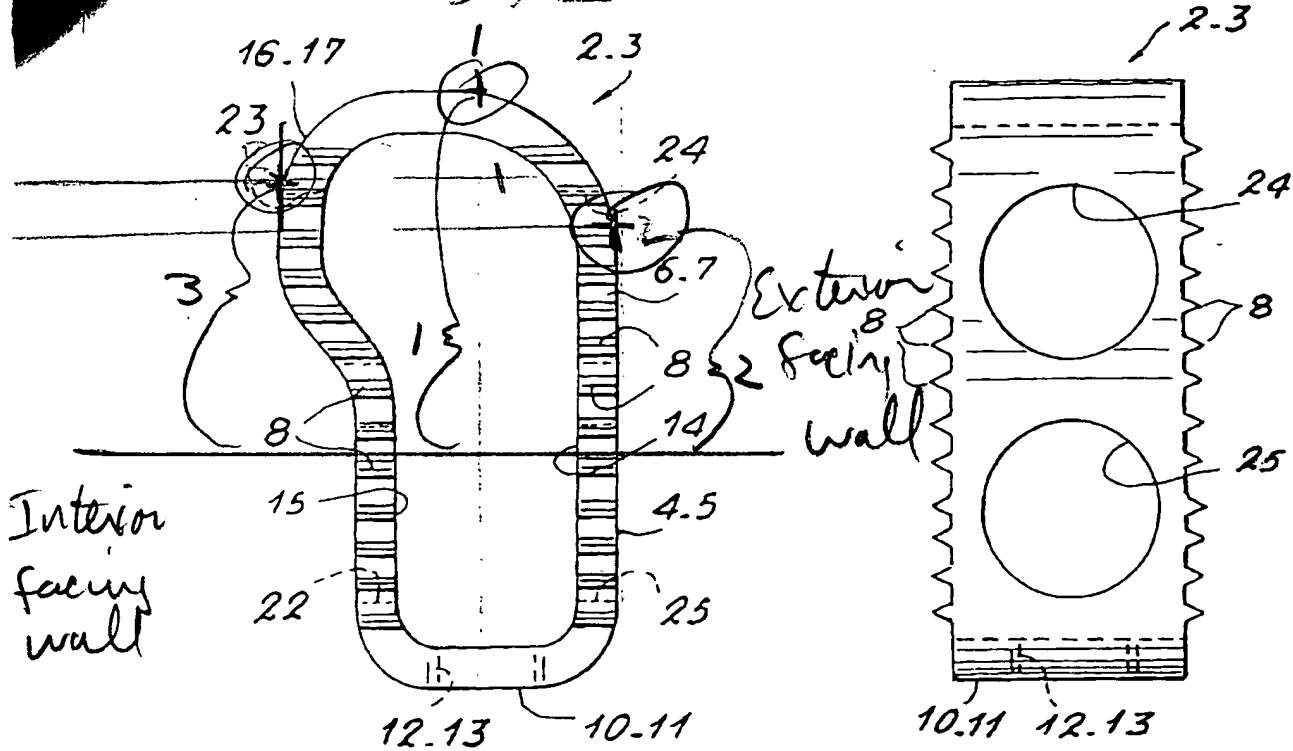


FIG. 2

FIG. 3

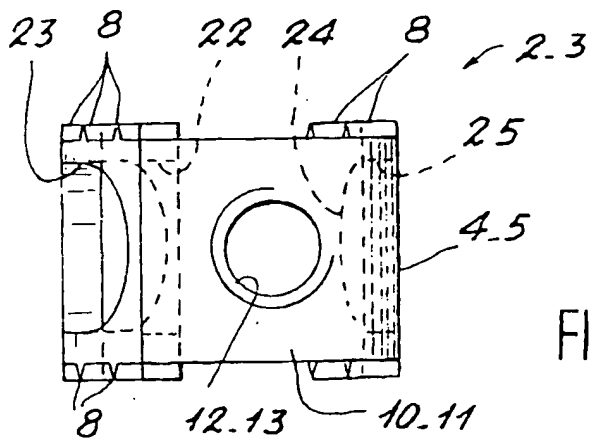


FIG. 4